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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,138	06/16/2005	Kanou Takeuchi	TAKEUCHI10	2221
1444 7590 10/11/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER LAU, JONATHAN S	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,138

Applicant(s)

TAKEUCHI ET AL.

Examiner

Jonathan S. Lau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9,12-15,17 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,12-15,17 and 40-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2 pages/10 Feb 2006.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

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DETAILED ACTION

This application is the national stage entry of PCT/JP03/16047, filed 15 Dec 2003, claiming benefit of foreign priority documents JAPAN 2002-368153, filed 19 Dec 2002; JAPAN 2003-62117, filed 07 Mar 2003; JAPAN 2003-86567, filed 26 Mar 2003; JAPAN 2003-163732, filed 09 Jun 2003; JAPAN 2003-349976, filed 10 Aug 2003. Claims 1-5, 8, 9, 12-15, 17 and 40-46 are pending and examined on the merits herein.

Examiner acknowledges receipt of the IDS filed 10 Feb 2006, filed before the mailing date of the first Office Action on the merits.

Election/Restrictions

Applicant's election with traverse of the invention of Group I in the reply filed on 24 Sep 2007 is acknowledged. The traversal is on the ground(s) that the moisture variation in a composition inhibited by incorporating a saccharide derivative of α,α -trehalose is not disclosed by Maruta et al. (US Patent 6,017,899), nor would any such subject matter have obvious from Maruta et al. This is not found persuasive because Maruta et al. discloses the osmotic pressure-controlling ability, moisture-retaining ability, and ability to prevent retrogradation of gelatinized starch of the trehalose derivatives disclosed. See Maruta et al. column 12, lines 21-25. Further, the argument regarding the serious burden required to examine the inventions of Groups I-III together citing U.S. restriction practice described in paragraph 2 of MPEP 803 is not persuasive because a showing of serious burden is not required to justify that the inventions of Groups I-III lack unity of invention.

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The requirement is still deemed proper. However, to facilitate prosecution of the instant application the restriction requirement is WITHDRAWN.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION:
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities:

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As recited above, each of the section headings should appear in upper case, without underlining or bold type. In the instant applications the section headings appear to be underlined and in bold type, and

Minor spelling errors such as:

Page 16, line 28, "egg york",

Page 18, line 5, "viscus".

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 9, 12-15, 17 and 40-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandai et al. (US Patent 5,780,620, issued 14 Jul 1998, cited in PTO-892).

Mandai et al. disclose an alpha-glucosyl saccharide bearing a trehalose structure at its end with a glucose polymerization degree of 3 or higher (column 2, lines 38-41

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and 66-67), in particular having 1, 2, 3, 4, or 5 glucose molecules and 1 trehalose molecules. See Mandai et al. column 11, lines 20-26. Broadly construed the trehalose is an end group of each of the glucosyl groups that are bound to the trehalose (instant claims 3, 14, and 42), as described in column 2, lines 1-2. Mandai et al. disclose the oligosaccharide is useful for the production of food products and compositions including cosmetics and pharmaceuticals as a moisture-controlling agent. See Mandai et al. column 5, lines 29-34 and column 6, lines 58-60. The drying agent comprises at least 10% of the total weight of the moisture inhibiting agent of the non-crystalline, or amorphous, oligosaccharide powder containing multiple, for example disclosed in Example A-9 on column 19, lines 10-14. (instant claims 12-15) One embodiment disclosing the production of a composition wherein the trehalose derivative is incorporated in an amount of at least ten percent of the total weight of said composition on a dry solid basis is disclosed in Example B-6 on column 20, lines 25- 44, wherein 50 parts by weight of maltosyl maltoside trehalose (instant claims 1-3 and 40-42), in the form of an amorphous powder (instant claim 4 and 43) are combined with 33 parts by weight of dried orange juice, 10 parts by weight sucrose (instant claims 5, 17 and 44-45), 0.65 parts by weight of citric anhydride, 0.1 part of malic acid, 0.1 parts by weight of L-ascorbic acid, 0.1 part by weight of sodium citrate, 0.5 parts by weight of pullulan and an appropriate amount of powdered flavoring agent to homogeneity to prepare a powdered juice composition (instant claims 8-9 and 46), and wherein the product is free of undesirable moisture intake.

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Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota et al. (US Patent 5,908,767, issued 1 Jun 1999, cited in PTO-892).

Kubota et al. discloses non-reducing saccharides bearing at their ends trehalose structures with glucose polymerization degrees of 3 or higher (column 2, lines 46-49), specifically trehalose with one, two, three, four, or five glucose molecules attached (column 16, lines 37-45), which possess desirable properties of osmosis controlling ability, moisture retaining ability, and ability to prevent retrogradation of gelatinized starch. See Kubota et al. column 10, lines 15-21. Kubota et al. discloses the use of the trehalose derivative as a desiccant in food products, cosmetics, medicines, and materials. See Kubota et al. column 10, lines 30-34. Kubota et al. disclose incorporating the trehalose derivative in compositions wherein the trehalose is incorporated in an amount of at least one percent to the total weight of said composition on a dry solid basis, for example in Example B-4 wherein three parts by weight gum base are combined with 4 parts sucrose and 3 parts by weight of a crystalline trehalose hydrate powder. See Kubota et al. column 38, lines 40-46. Kubota et al. disclose incorporating the amorphous trehalose derivative into a food composition wherein the trehalose is incorporated in an amount of at least one percent to the total weight of said composition on a dry solid basis (instant claims 8-9), for example in Example B-2 wherein one hundred parts by weight of 55% sucrose solution was mixed with 30 parts by weight of a syrup containing non-reducing saccharides obtained by the method in Example A-1 while heating, concentrated by heating in vacuo to a moisture content lower than 2%, admixed with one part by weight of citric acid and appropriate amounts

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of lemon flavor and coloring agent and shaped in a conventional manner to obtain products. The products are high-quality hard candies which are crisp, superior in taste and free of crystallization of sucrose and deformation. See Kubota et al. column 38, lines 10-20.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 12-15, 17 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubota et al. (US Patent 5,908,767, issued 1 Jun 1999, cited in PTO-892).

Kubota et al. discloses non-reducing saccharides bearing at their ends trehalose structures with glucose polymerization degrees of 3 or higher (column 2, lines 46-49), specifically trehalose with one, two, three, four, or five glucose molecules attached (column 16, lines 37-45) (instant claims 3, 14, and 42); which possess desirable properties of osmosis controlling ability, moisture retaining ability, and ability to prevent retrogradation of gelatinized starch. See Kubota et al. column 10, lines 15-21. Kubota et al. discloses the use of the trehalose derivative as a desiccant in food products, cosmetics, medicines, and materials. See Kubota et al. column 10, lines 30-34. Kubota et al. discloses the use of the trehalose derivative in combination with starch syrup powder, glucose, maltose, or sucrose. See Kubota et al. column 10, lines 45-47. Kubota et al. disclose preparations of both the crystalline trehalose derivative (see Example A-5 in column 35, lines 15-20) and an amorphous trehalose derivative in which the trehalose derivative is not crystallized (see Example A-1 in column 33, lines 23-25) in which the trehalose derivative is at least 10% of the total weight of the trehalose derivative-containing agent (instant claims 12-15 and 17). Kubota et al. disclose incorporating the trehalose derivative in compositions wherein the trehalose is incorporated in an amount of at least one percent to the total weight of said composition on a dry solid basis (instant claims 1-3 and 40-42), for example in Example B-4 wherein

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three parts by weight gum base are combined with 4 parts sucrose and 3 parts by weight of a crystalline trehalose hydrate powder (instant claims 8-9 and 46). See Kubota et al. column 38, lines 40-46. Kubota et al. disclose incorporating the amorphous trehalose derivative (instant claim 4 and 43) into a food composition (instant claims 8-9 and 46) wherein the trehalose is incorporated in an amount of at least ten percent of the total weight of said composition on a dry solid basis (instant claims 1-3 and 40-42), for example in Example B-2 wherein one hundred parts by weight of 55% sucrose solution (instant claims 5 and 44-45) was mixed with 30 parts by weight of a syrup containing non-reducing saccharides obtained by the method in Example A-1 while heating, concentrated by heating in vacuo to a moisture content lower than 2%, admixed with one part by weight of citric acid and appropriate amounts of lemon flavor and coloring agent and shaped in a conventional manner to obtain products. The products are high-quality hard candies which are crisp, superior in taste and free of crystallization of sucrose and deformation. See Kubota et al. column 38, lines 10-20.

Kubota et al. does not specifically disclose the property of inhibiting moisture variation in a composition by incorporating the trehalose derivative into said composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the moisture variation in the composition incorporating the trehalose derivative would be inhibited. Kubota et al. discloses that the trehalose derivative possesses the desirable properties of moisture retaining ability, and ability to prevent retrogradation of gelatinized starch. See Kubota et al. column 10, lines 15-21. It would

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have been obvious to one of ordinary skill in the art at the time of the invention to use the desirable properties of moisture retaining ability, and ability to prevent retrogradation of gelatinized starch of the trehalose derivative or that these desirable properties would be inherently included in the disclosed compositions incorporating the trehalose derivative.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-9 and 12-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-15 and 1-2 respectively of U.S. Patent No. 5,780,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because while claims 1-2 and 12-15 do not specifically claim the property of inhibiting moisture variation in the composition, the specification of U.S. Patent No. 5,780,620 discloses the trehalose derivative is useful for the production of food products and compositions including cosmetics and pharmaceuticals as a moisture-controlling agent. See Mandai et al. column 5, lines 29-34 and column 6, lines 58-60. Instant claims 12-14 claim a saccharide derivative of alpha,alpha-trehalose in an amount of at least 10% of the total weight of the agent. Claim 1 of U.S. Patent No. 5,780,620 claims alpha,alpha-trehalose connected to two glucosyl groups, which is an agent in which the saccharide derivative of alpha,alpha-trehalose is 100% of the total weight of the agent. Claim 2 of U.S. Patent No. 5,780,620 claims alpha,alpha-trehalose connected to two maltose (diglucose) groups. Broadly construed the trehalose is an end group of each of the glucosyl groups that are bound to the trehalose (instant claim 14), as described in column 2, lines 1-2 of U.S. Patent No. 5,780,620. Claim 13 of U.S. Patent No. 5,780,620 recites the limitation of a composition wherein the oligosaccharide is about 0.1 w/w% or more, however the embodiment of a composition wherein the trehalose is incorporated in an amount of at least one percent of the total weight of said composition on a dry solid basis is disclosed

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in Example B-6 on column 20, lines 25- 44 of U.S. Patent No. 5,780,620 renders obvious the instant claims 8 and 9, wherein the trehalose derivative is present in an amount of at least one percent by weight of the composition.

Instant claims 8 and 9 recite a product-by-process. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Conclusion

No claim is found to be allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

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3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER